(c) by when Government propose to lake a final decision in this regard?

THE MINISTER OF STATE IN ' THE DEPARTMENT QF CHEMICALS AND FETRO-CHEMICALS IN THE MINISTRY OF INDUSTRY (8HRI R. K. JAICHANDRA SINGH):

(a) No, Sir. (b) and (c) Do not arise.

Unauthorised production of medicines

1505. SHRI RAFIQUE ALAM: Will the Minister of INDUSTRY be pleased to state;

(a) whether it is a fact that the Hathi Committee recommended not to regularise unauthorised production of medicines;

(b) if so, what are the basis of such recommendations;

(c) whether it is also a fact that Drug Policy, 1978 does not permit regularisation of unauthorised production;

(d) whether it is a fact that his Ministry has proposed regularisation of unauthorised production;

(e) whether it is also a fact that majority of the formulations under unauthorised production are non-essential and •useless;

(£)• the names of the drug companies alongwith names of formulations of each company whose production was found of doubtful validity;

(g) name of "the category under which each formulation falls;

-(h) whether it is a fact that no case by case study lias been made; and

(i) if so, what arc the reasons for such regularisation in spite of prohibition by Hathi Committee?

THE MINISTER OF STATE IN THE DEPARTMENT OF CHEMICALS AND PEJRO-CHEMICALS IN THE MINISTRY OF INDUSTRY (SHRI R. K. JAICHANDRA SINGH); <a) Yes, Sir.

(b) The report of the Hathi Committee was laid on the Table o£ the House and is available in the- Parliament library which indicates details of its recommendations.

(c>»Thc 1978 Drug Policy does not provide for regularisation of unauthorised production.

(d) The series of measures announced by the Government in December. 1986 provide for regularisation of such production.

(e) No, Sir.

(f) Information is given in Annettne *[See* Appendix CXLH, anneure No. 73].

(g) Items of doubtful validity can be classified into the following group:-: ,

(1) Items claimed to be cohered under Registration Certificates issued under Section 10 of the KD&R) Act.

(2) Items claimed under exemptions from industrial licensing but in respect of which no COB licences were obtained after the .said exemptions were withdrawn.

(3) Items with a composition different from that already authorised and hence amounting to manufacture of new articles.

(4) Items not covered by any approval under the I(D&R) Act.

(h) and (i) An Inter-Ministerial Working Group was set up in 1982 to examine the question of production of drugs with valid approval and to suggest possible lines of action that may be .taken. Details of measures for regularisation. quality control and growth of pharmaceutical industry in India giving rational oC each of the decision have already been laid on the Table of the House in reply to various questions and are also available in the library of the Parliament.